

OTC Ingredient List
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Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
danthron						
laxative	laxative		stimulant laxative	I	IIS	310.545(a)(12)(iv)(B)
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d-calcium pantothenate [see calcium pantothenate]						
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dehydrocholic acid						
laxative	laxative		stimulant laxative	I	I	pending
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IIE	IIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIE	IIE	310.545(a)(8)(i)
denatonium benzoate						
miscellaneous external	nailbiting/thumbsucking		nailbiting/thumbsucking deterrent	IIIIE	IIIIE	310.536(a)
dequalinium chloride						
oral cavity	oral health care		antimicrobial	IIISE	IIISE	pending
desoxyephedrine, l- [see levomethamphetamine]						
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dexbrompheniramine maleate						
cough/cold	cough/cold (antihistamine)		antihistamine	IIISE	I	341.12(d)
cough/cold	cough/cold (antihistamine)		antihistamine	n/a	I	341.12(f)
dexchlorpheniramine maleate						
cough/cold	cough/cold (antihistamine)		antihistamine	n/a	I	341.12(e)

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dexpanthenol						
=====	external analgesic		poison ivy/oak/sumac	n/a	IIIIE	310.545(a)(10)(vii)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	external analgesic		insect bite/sting	n/a	IIIIE	pending
miscellaneous external	hair growth/loss		hair grower	n/a	IIE	310.527(a)
miscellaneous external	skin protectant		diaper rash	defer	IIISE	pending
dextran 70						
ophthalmic	ophthalmic		demulcent	I	I	349.12(b)
dextromethorphan						
cough/cold	cold/cough (antitussive)		antitussive	I	I	341.14(a)(3)
dextromethorphan hydrobromide						
cough/cold	cough/cold (antitussive)		antitussive	n/a	n/a	341.14(a)(4)
dextrose						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
diastase						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
diastase malt						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)

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dibenzothiophene						
antimicrobial II	acne		acne	IIS	IIS	310.545(a)(1)
dibucaine						
=====	external analgesic		poison ivy/oak/sumac	n/a	I	pending
hemorrhoidal	anorectal		anesthetic (intrarectal)	IIISE	IIISE	[55 FR 1779]
hemorrhoidal	anorectal		anesthetic (external)	IIIS	I	346.10(d)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	IISE	310.545(a)(10)(iv)
miscellaneous external	external analgesic		fever blister (topical)	defer	I	pending
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
oral cavity	oral health care		analgesic/anesthetic	IIS	IIS	310.545(a)(14)
topical analgesic	external analgesic		analgesic/anesthetic	I	I	pending
dibucaine hydrochloride						
=====	external analgesic		fever blister (topical)	n/a	I	pending
=====	external analgesic		poison ivy/oak/sumac	n/a	I	pending
hemorrhoidal	anorectal		anesthetic (external)	IIIS	I	346.10(c)
hemorrhoidal	anorectal		anesthetic (intrarectal)	IIISE	IIISE	[55 FR 1779]
oral cavity	oral health care		analgesic/anesthetic	IIS	IIS	310.545(a)(14)

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	topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
dicalcium phosphate dihydrate [see calcium phosphate, dibasic]						
====	====	gingivitis/plaque	gingivitis/antiplaque	n/a	IIIIE	pending
dichlorodiphenyl trichloroethane [see chorophenothane]	====	====	====	====	====	====
dichlorophen						
antimicrobial II	antifungal		antifungal	IIISE	IIISE	310.545(a)(22)(ii)
miscellaneous external	hair growth/loss		hair grower	IISE	n/a	310.527(a)
diethanolamine methoxycinnamate						
topical analgesic	sunscreen		sunscreen	I	I	310.545(a)(29)
diethanolamine p-methoxy-cinnamate [see diethanolamine methoxycinnamate]	====	====	====	====	====	====
digalloyltriolate						
topical analgesic	sunscreen		sunscreen	I	I	310.545(a)(29)
dihydroxyaluminum aminoacetate						
antacid	antacid		antacid	I	I	331.11(a)(3)
dihydroxyaluminum aminoacetic acid						
antacid	antacid		antacid	n/a	n/a	331.11(a)(3)
internal analgesic	internal analgesic		corrective	I	n/a	n/a

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dihydroxyaluminum sodium carbonate						
antacid		antacid	antacid	I	I	331.11(a)(5)
internal analgesic		internal analgesic	corrective	I	n/a	n/a
miscellaneous internal		digestive aid	digestive aid (ippuad)	IIIIE	IIIIE	310.545(a)(8)(i)
dimenhydrinate						
laxative		antiemetic	antiemetic	I	I	336.10(b)
dimethicone						
====		skin protectant	diaper rash	n/a	I	pending
====		skin protectant	fever blister (topical)	n/a	I	pending
topical analgesic		skin protectant	skin protectant	I	I	347.10(g)
dimethisoquin hydrochloride						
====		external analgesic	poison ivy/oak/sumac	n/a	I	pending
====		external analgesic	fever blister (topical)	n/a	I	pending
topical analgesic		external analgesic	analgesic/anesthetic	I	I	pending
dioxybenzone						
topical analgesic		sunscreen	sunscreen	I	I	352.10(e)
diperodon						
hemorrhoidal		anorectal	anesthetic (intrarectal)	IIISE	IIISE	310.545(a)(26)(vi)
hemorrhoidal		anorectal	anesthetic (external)	IIE	IIIIE	310.545(a)(26)(vi)

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diperodon hydrochloride						
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)(A)
miscellaneous external	corn/callus remover		corn/callus remover	IISE	IISE	[55 FR 33261]
diphenhydramine citrate						
cough/cold	cough/cold (antitussive)		antitussive	n/a	n/a	341.14(a)(5)
cough/cold	cough/cold (antihistamine)		antihistamine	n/a	n/a	341.12(f)
sedative	nighttime sleep aid		sleep aid	n/a	n/a	338.10(b)
diphenhydramine hydrochloride						
====	external analgesic		fever blister (topical)	n/a	I	pending
cough/cold	cough/cold (antitussive)		antitussive	I	IIIIE	341.14(a)(6)
cough/cold	cough/cold (antihistamine)		antihistamine	I	I	341.12(g)
laxative	antiemetic		antiemetic	IIIIE	IIIIE	336.10(c)
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	I	pending
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)

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	sedative	daytime sedative	sedative	I	I	310.519(a)
	sedative	nighttime sleep aid	sleep aid	II	II	336.10(a)
	topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
diphenhydramine monocitrate [see diphenhydramine citrate]						
====	====	====	====	====	====	====
dipropylene glycol salicylate						
topical analgesic		sunscreen	sunscreen	II	II	[64 FR 27682]
dl-methionine [see racemethionine]						
====	====	====	====	====	====	====
docusate calcium						
laxative		laxative	stool softener	I	I	pending
docusate potassium						
laxative		laxative	stool softener	I	I	pending
docusate sodium						
contraceptive/vaginal	vaginal		lowers surface tension mucolytic effects	I	withdraw	n/a
laxative		laxative	stool softener	I	I	pending
miscellaneous external	pediculicide		pediculicide	II	II	310.545(a)(25)(i)
miscellaneous internal	weight control		anorectic	II	II	310.545(a)(20)

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dodecaethylene glycol monolaurate			contraceptive	IIIIE	withdraw	310.545(a)(28)
contraceptive/vaginal	contraceptive (vaginal)					
=====	=====	=====	=====	=====	=====	=====
dog grass						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
domiphen bromide						
oral cavity	oral health care		antimicrobial	IIISE	IIISE	pending
don qual						
miscellaneous internal	aphrodisiac		aphrodisiac	IISE	IISE	310.528(a)
doxylamine succinate						
cough/cold	cough/cold (antihistamine)		antihistamine	I	I	341.12(h)
sedative	daytime sedative		sedative	IISE	IISE	310.519(a)
sedative	nighttime sleep aid		sleep aid	IIISE	IIISE	[54 FR 6826]
duodenal substance						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IISE	IISE	310.545(a)(8)(i)

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dyclonine hydrochloride						
	=====	external analgesic	fever blister (topical)	n/a	I	pending
	=====	external analgesic	poison ivy/oak/sumac	n/a	I	pending
	hemorrhoidal	anorectal	anesthetic (external)	IIIIE	I	346.10(e)
	hemorrhoidal	anorectal	anesthetic (intrarectal)	IIIIE	IIIIE	[55 FR 1779]
	oral cavity	oral health care	analgesic/anesthetic	I	I	pending
	topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
e. coli vaccines						
	hemorrhoidal	anorectal	anorectal (external)	IIISE	IIISE	310.545(a)(26)(vii)
	hemorrhoidal	anorectal	anorectal (intrarectal)	IIISE	IIISE	310.545(a)(26)(vii)
edetate disodium						
	contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a
	dental	relief of oral discomfort	tooth desensitizer (in combination only)	IIISE	IIISE	pending
edetate sodium						
	contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a
elaterin resin						
	laxative	laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)
elecampane						
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)

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elm bark						
cough/cold		cough/cold (antitussive)	antitussive	IIIIE	IIIIE	[52 FR 30054]
oral cavity		oral health care	demulcent	I	I	pending
endothermic hectorite [see hectorite]						
====	====	====	====	====	====	====
ensulizole						
topical analgesic		sunscreen	sunscreen	I	I	352.10(n)
ephedrine						
cough/cold		cough/cold (bronchodilator)	bronchodilator	I	I	341.16(a)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	I	I	341.20(b)(1)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (oral)	IIIIE	IIIIE	310.545(a)(6)(ii)(B)
ephedrine (any ingredient)						
====		menstrual/diuretic	menstrual	n/a	n/a	310.545(a)(24)(ii)
====		internal analgesic	analgesic	n/a	n/a	310.545(a)(23)(ii)
ephedrine hydrochloride						
cough/cold		cough/cold (bronchodilator)	bronchodilator	I	I	341.16(b)
miscellaneous external		MALE GENITAL DESENSITIZER	male genital desensitizer	IISE	IISE	310.545(a)(10)(iii)
ophthalmic		ophthalmic	vasoconstrictor	I	I	349.18(a)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (oral)	IIIIE	IIIIE	310.545(a)(6)(ii)(B)

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	cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	I	I	341.20(b)(3)
ephedrine sulfate						
cough/cold	cough/cold (bronchodilator)	bronchodilator		I	I	341.16(c)
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)		I	I	341.20(b)(4)
hemorrhoidal	anorectal	vasoconstrictor (intrarectal)		I	I	346.12(a)
hemorrhoidal	anorectal	vasoconstrictor (external)		I	I	346.10(a)
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (oral)		IIIIE	IIIIE	310.545(a)(6)(ii)(B)
epinephrine						
cough/cold	cough/cold (bronchodilator)	bronchodilator (inhalation)		I	I	341.16(d)
hemorrhoidal	anorectal	vasoconstrictor (external)		IIISE	I	346.10(b)
hemorrhoidal	anorectal	vasoconstrictor (intrarectal)		IIISE	IIISE	346.10(b)
epinephrine bitartrate						
cough/cold	cough/cold (bronchodilator)	bronchodilator (inhalation)		I	I	341.16(e)
epinephrine hydrochloride						
hemorrhoidal	anorectal	vasoconstrictor (external)		I	I	346.10(c)
hemorrhoidal	anorectal	vasoconstrictor (intrarectal)		IIE	IIE	346.10(c)
epinephrine hydrochloride (racemic) [see epinephrine hydrochloride]						
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epinephrine undecylenate						
hemorrhoidal		anorectal	vasoconstrictor (external)	IIISE	IIISE	310.545(a)(26)(ix)
hemorrhoidal		anorectal	vasoconstrictor (intrarectal)	IIE	IIE	310.545(a)(26)(ix)
ergocalciferol						
contraceptive/vaginal	vaginal		minor irritations	IIIIE	withdraw	n/a
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
ergot fluidextract						
miscellaneous external	boil treatment		boil treatment	IISE	IISE	310.531(a)
miscellaneous external	external analgesic		insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
miscellaneous external	skin protectant		insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)
escalol 506 [see padimate a]						
=====	=====	=====	=====	=====	=====	=====
essential oils						
miscellaneous external	hair growth/loss		hair grower	IISE	n/a	310.527(a)

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estradiol						
	miscellaneous external	hair growth/loss	hair grower	IIE	IIE	310.527(a)
estrogens						
	miscellaneous external	hormone	hormone	IIE	IIE	310.530(a)
	miscellaneous internal	aphrodisiac	aphrodisiac	IIS	IIS	310.528(a)
estrone						
	antimicrobial II	acne	acne	IISE	IISE	310.545(a)(1)
ether						
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
ethohexadiol						
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	IIIIE	IIIIE	310.545(a)(7)
ethoxylated alkyl alcohol						
	miscellaneous external	analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
	miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)
ethyl 4-(bis (hydroxypropyl)) aminobenzoate						
	topical analgesic	sunscreen	sunscreen	I	I	310.545(a)(29)
ethyl alcohol [see alcohol]						
	=====	=====	=====	=====	=====	=====

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ethyl nitrate			diuretic	n/a	IISE	310.545(a)(24)(i)
miscellaneous internal menstrual/diuretic						
ethylhexyl p-methoxycinnamate [see white pine extract, compound]	=====	=====	=====	=====	=====	=====
ethylmorphine hydrochloride						
cough/cold	cough/cold (antitussive)	antitussive	IIIIE	IIIIE	[52 FR 30054]	
eucalyptol						
cough/cold	cough/cold (antitussive)	antitussive (topical/inhalant)	IIIIE	IIIIE	[52 FR 30055]	
cough/cold	cough/cold (antitussive)	antitussive (mouthwash)	IIIIE	IIIIE	[52 FR 30055]	
cough/cold	cough/cold (antitussive)	antitussive (lozenge)	IIIIE	IIIIE	[52 FR 30054]	
cough/cold	cough/cold (expectorant)	expectorant (lozenge)	IIIIE	IIIIE	310.545(a)(6)(iii)	
cough/cold	cough/cold (expectorant)	expectorant (topical/inhalant)	IIIIE	IIIIE	310.545(a)(6)(iii)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IIIIE	IIIIE	310.545(a)(6)(ii)(A)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (mouthwash)	IIIIE	IIIIE	310.545(a)(6)(ii)(A)	
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (lozenge)	IIIIE	IIIIE	310.545(a)(6)(ii)(A)	
miscellaneous external antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)	
miscellaneous external antimicrobial		diaper rash	defer	n/a	pending	
miscellaneous external dandruff/seborrheic dermatitis/psoriasis	dandruff		IIIIE	IIIIE	310.545(a)(7)	
miscellaneous external external analgesic		diaper rash	defer	IISE	310.545(a)(10)(iv)	

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	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
oral cavity		oral health care	antimicrobial	IIIIE	IIIIE	pending
oral cavity		oral health care	analgesic/anesthetic	IIIIE	IIIIE	310.545(a)(14)
eucalyptol, menthol, methyl salicylate, and thymol						
====		gingivitis/plaque	antiplaque/gingivitis	n/a	I	pending
eucalyptus oil						
====		external analgesic	fever blister (topical)	n/a	IIIIE	310.545(a)(10)(v)
cough/cold		cough/cold (antitussive)	antitussive (mouthwash)	IIIIE	IIIIE	[52 FR 30055]
cough/cold		cough/cold (antitussive)	antitussive (lozenge)	IIIIE	IIIIE	[52 FR 30054]
cough/cold		cough/cold (antitussive)	antitussive (topical/inhalant)	IIIIE	IIIIE	[52 FR 30055]
cough/cold		cough/cold (expectorant)	expectorant (lozenge)	IIIIE	IIIIE	310.545(a)(6)(iii)
cough/cold		cough/cold (expectorant)	expectorant (topical/inhalant)	IIIIE	IIIIE	310.545(a)(6)(iii)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (mouthwash)	IIIIE	IIIIE	310.545(a)(6)(ii)(A)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (inhalant room spray)	IIIIE	IIIIE	[59 FR 43408]
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (lozenge)	IIIIE	IIIIE	310.545(a)(6)(ii)(A)
miscellaneous external		antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external		antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external		external analgesic	astringent	IISE	n/a	pending
miscellaneous external		external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)

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	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
	miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)
	miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)
	miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)
	topical analgesic	external analgesic	counterirritant	IIIIE	IIIIE	310.545(a)(10)(ii)
eugenol						
====		external analgesic	poison ivy/oak/sumac	n/a	IIIIE	310.545(a)(10)(vii)
dental		relief of oral discomfort	toothache relief	I	IIISE	pending
miscellaneous external	external analgesic		astringent	IISE	n/a	pending
miscellaneous external	external analgesic		fever blister (topical)	defer	IIIIE	310.545(a)(10)(v)
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
topical analgesic	external analgesic		analgesic/anesthetic	IIIIE	IIIIE	310.545(a)(10)(i)
euphorbia pilulifera						
cough/cold		cough/cold (bronchodilator)	bronchodilator	IIIIE	IIIIE	310.545(a)(6)(iv)(A)
extract white pine compound [see white pine extract, compound]						
====	=====	=====	=====	=====	=====	=====

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fatty acids						
	miscellaneous external	hair growth/loss	hair grower	IIE	n/a	310.527(a)
fennel acid						
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
ferric ammonium citrate						
	miscellaneous internal	weight control	anorectic	IIE	IIE	310.545(a)(20)
ferric chloride						
	miscellaneous external	external analgesic	insect bite/sting	IIE	IIE	310.545(a)(10)(vi)
	miscellaneous external	skin protectant	insect bite/sting	IIE	IIE	310.545(a)(18)(v)(A)
	miscellaneous external	skin protectant	poison ivy/oak/sumac	IIE	IIE	310.545(a)(18)(vi)(A)
	miscellaneous internal	menstrual/diuretic	diuretic	n/a	IIE	310.545(a)(24)(i)
	oral cavity	oral health care	antimicrobial	IIE	IIE	pending
ferric pyrophosphate						
	miscellaneous internal	weight control	anorectic	IIE	IIE	310.545(a)(20)
ferric subsulfate						
	miscellaneous external	external analgesic	astringent	IIE	n/a	pending
	miscellaneous external	skin protectant	astringent	IIE	IIE	310.545(a)(18)(ii)
ferrous fumarate						
	miscellaneous internal	weight control	anorectic	IIE	IIE	310.545(a)(20)

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ferrous gluconate						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
ferrous sulfate						
	miscellaneous internal	menstrual/diuretic	premenstrual/menstrual period	n/a	IISE	310.545(a)(24)(i)
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
flax seed						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
fluid extract ergot [see ergot, fluidextract]	=====	=====	=====	=====	=====	=====
fluorosalan						
	antimicrobial I	antimicrobial	antimicrobial	IIS	IIS	pending
folic acid						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
formaldehyde solution						
	dental	relief of oral discomfort	tooth desensitizer	IIIIE	IIIIE	pending
formic acid						
	miscellaneous external	pediculicide	pediculicide	n/a	n/a	310.545(a)(25)(i)
frangula						
	laxative	laxative	stimulant laxative	IIISE	IIISE	310.545(a)(12)(iv)(A)

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fructose						
	miscellaneous internal	overindulgence in alcohol/food	minimize inebriation	IIIIE	IIIIE	[48 FR 32873]
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
galega						
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
gamboge						
	laxative	laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)
garlic, dehydrated						
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIE	IIE	310.545(a)(8)(i)
	miscellaneous internal	digestive aid	digestive aid (ippuad)	IIE	IIE	310.545(a)(8)(i)
gastric mucin						
	antacid	antacid	antacid	IIIIE	IIIIE	[39 FR 19873]
gelatin						
	oral cavity	oral health care	demulcent	I	I	pending
	ophthalmic	ophthalmic	demulcent	I	I	349.12(c)
gentian violet						
	miscellaneous internal	anthelmintic	anthelmintic	I	IIS	[51 FR 27758]
	oral cavity	oral health care	antimicrobial	IIIIE	IIE	pending

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gentiana lutea (gentian)						
miscellaneous internal	menstrual/diuretic		premenstrual/menstrual period	n/a	IISE	310.545(a)(24)(i)
ginger						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
ginger, ground [see ginger, jamaica]	=====	=====	=====	=====	=====	=====
ginger, jamaica						
miscellaneous internal	smoking deterrent		smoking deterrent	IIE	IIE	310.544(d)
ginseng						
miscellaneous internal	aphrodisiac		aphrodisiac	IISE	IISE	310.528(a)
sedative	stimulant		stimulant	IIE	IIE	[39 FR 6104]
ginseng, korean						
miscellaneous internal	aphrodisiac		aphrodisiac	IISE	IISE	310.528(a)
glutamic acid						
miscellaneous internal	benign prostatic hypertrophy		benign prostatic hypertrophy	IIE	IIISE	310.532(a)
glutamic acid hydrochloride						
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIE	IIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IIE	IIE	310.545(a)(8)(i)
miscellaneous internal	stomach acidifier		stomach acidifier	IIE	IIE	310.540(a)

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glycerin						
hemorrhoidal	anorectal		antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)
hemorrhoidal	anorectal		antiseptic (external)	IISE	IISE	310.545(a)(26)(ii)
hemorrhoidal	anorectal		protectant (external)	I	I	346.14(3)
hemorrhoidal	anorectal		protectant (intrarectal)	I	I	346.14(3)
laxative	laxative		hyperosmotic laxative	I	I	pending
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	DEF	310.545(a)(10)(iv)
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant		diaper rash	defer	IIISE	310.545(a)(18)(iii)
miscellaneous external	skin protectant		fever blister (topical)	defer	I	pending
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
oral cavity	oral health care		demulcent	I	I	pending
ophthalmic	ophthalmic		demulcent	I	I	349.12(d)(1)
topical analgesic	otic		ear wax softening agent	I	IIIIE	[51 FR 28660]
topical analgesic	skin protectant		skin protectant	I	I	347.10(h)
glycerin, anhydrous						
=====	otic		drying water/water clogged ears	n/a	IIIIE	310.545(a)(15)(ii)

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=====	=====	otic	swimmer's ear prevention	n/a	IIIIE	310.545(a)(15)(ii)
glycerin, anhydrous [see glycerin]						
=====	=====	=====	=====	=====	=====	=====
glyceryl aminobenzoate						
topical analgesic	sunscreen		sunscreen	I	I	310.545(a)(29)
glycine						
antacid	antacid		antacid	I	I	331.11(f)
internal analgesic	internal analgesic		corrective	I	n/a	pending
laxative	antidiarrheal		antidiarrheal	IIIE	IIIE	310.545(a)(3)(i)
laxative	antiemetic		antiemetic	IIIE	IIIE	[52 FR 15891]
miscellaneous internal	benign prostatic hypertrophy		benign prostatic hypertrophy	IIIE	IIISE	310.532(a)
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
glycol salicylate						
=====	external analgesic		poison ivy/oak/sumac	n/a	IIIE	310.545(a)(10)(vii)
miscellaneous external	external analgesic		fever blister (topical)	defer	IIIE	310.545(a)(10)(v)
topical analgesic	external analgesic		analgesic/anesthetic	IIIE	IIIE	pending
glycyrrhiza						
miscellaneous internal	aphrodisiac		aphrodisiac	IIE	IISE	310.528(a)
miscellaneous internal	menstrual/diuretic		premenstrual/menstrual period	n/a	IISE	310.545(a)(24)(i)

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golden seal						
miscellaneous internal	aphrodisiac		aphrodisiac	IISE	IISE	310.528(a)
=====	=====	=====	=====	=====	=====	=====
gotu kola						
miscellaneous internal	aphrodisiac		aphrodisiac	IISE	IISE	310.528(a)
gramicidin						
antimicrobial II	antibiotic		first aid antibiotic	n/a	IIISE	[52 FR 47322]
antimicrobial II	antibiotic		skin wound protectant	IIS	defer	[52 FR 47322]
antimicrobial II	antibiotic		skin wound antibiotic	IIISE	defer	[52 FR 47322]
guaifenesin						
cough/cold	cough/cold (expectorant)		expectorant	IIIIE	IIIIE	341.18
guar gum						
laxative	laxative		bulk laxative	IIIIE	IIIIE	310.545(a)(12)(i)
miscellaneous internal	weight control		anorectic	IIIIE	IISE	310.545(a)(20)
haloprogin						
antimicrobial II	antifungal		anticandidal	I	n/a	n/a
antimicrobial II	antifungal		antifungal	I	I	333.210(b)

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hamamelis water of xi [see witch hazel]	=====	=====	=====	=====	=====	=====
hard fat						
	=====	skin protectant	skin protectant	n/a	n/a	347.10(i)
hemorrhoidal		anorectal	protectant (external)	n/a	n/a	346.14(4)
hemorrhoidal		anorectal	protectant (intrarectal)	n/a	n/a	346.14(4)
hectorite						
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
hemicellulase						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IIIIE	IIIIE	310.545(a)(8)(i)
miscellaneous internal	exocrine pancreatic insufficiency		exocrine pancreatic insufficiency	IIE	IIE	310.543(a)
hexachlorophene						
antimicrobial I	antimicrobial		antimicrobial	IIS	n/a	[37 FR 20163]
contraceptive/vaginal	vaginal		minor irritations	IISE	withdraw	n/a
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	IISE	pending
miscellaneous external	boil treatment		boil treatment	IISE	IISE	310.531(a)

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	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
hexylresorcinol						
=====		external analgesic	poison ivy/oak/sumac	n/a	III E	310.545(a)(10)(vii)
antimicrobial I		antimicrobial	antimicrobial soap	n/a	III E	pending
antimicrobial I		antimicrobial	first aid antiseptic	n/a	I	pending
antimicrobial I		antimicrobial	health care personnel handwash	III E	III E	pending
antimicrobial I		antimicrobial	preoperative skin prep	III E	III E	pending
antimicrobial I		antimicrobial	skin antiseptic	III E	III E	pending
antimicrobial I		antimicrobial	skin wound cleanser	I	I	pending
antimicrobial I		antimicrobial	skin wound protectant	III E	III E	pending
antimicrobial I		antimicrobial	surgical hand scrub	III E	III E	pending
miscellaneous external		external analgesic	fever blister (topical)	defer	III E	310.545(a)(10)(v)
oral cavity		oral health care	analgesic/anesthetic	I	I	pending
topical analgesic		external analgesic	analgesic/anesthetic	III E	III E	310.545(a)(10)(i)
histamine dihydrochloride						
miscellaneous external		external analgesic	fever blister (topical)	defer	II SE	310.545(a)(10)(v)
topical analgesic		external analgesic	counterirritant	I	I	pending

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histidine						
	miscellaneous internal	weight control	anorectic	I	I	310.545(a)(20)
homatropine methylbromide						
laxative		antidiarrheal	antidiarrheal	I	I	310.545(a)(3)
miscellaneous internal		digestive aid	digestive aid (intestinal distress)	III	III	310.545(a)(8)(i)
miscellaneous internal		digestive aid	digestive aid (ippuad)	II	II	310.545(a)(8)(i)
miscellaneous internal		menstrual/diuretic	smooth muscle relaxant	II	III	310.545(a)(24)(i)
homosalate						
miscellaneous external		external analgesic	fever blister (topical)	defer	defer	pending
topical analgesic		n/a	sunscreen	n/a	I	352.10(f)
honey						
miscellaneous external		external analgesic	astringent	I	n/a	pending
miscellaneous external		skin protectant	astringent	I	II	310.545(a)(18)(ii)
horehound						
cough/cold		cough/cold (antitussive)	antitussive	III	III	[52 FR 30054]
oral cavity		oral health care	expectorant	III	III	310.545(a)(6)(iii)
hormone constituents						
miscellaneous external		hair growth/loss	hair grower	I	II	310.527(a)

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horsetail						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
huckleberry						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
hyascyamine sulfate						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
hydrangea, powdered extract (extract of hydrangea)						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
hydrastis						
hemorrhoidal	anorectal		counterirritant (intrarectal)	IISE	IISE	310.545(a)(26)(iv)
hemorrhoidal	anorectal		antiseptic (external)	IISE	IISE	310.545(a)(26)(iv)
hemorrhoidal	anorectal		counterirritant (external)	IISE	IISE	310.545(a)(26)(iv)
hemorrhoidal	anorectal		antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)
miscellaneous internal	aphrodisiac		aphrodisiac	IISE	IISE	310.528(a)
hydrastis canadensis (golden seal)						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	menstrual/diuretic		menstrual	n/a	IISE	310.545(a)(24)(i)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)

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hydrastis fluid extract						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
hydrate magnesium aluminate activated sulfate						
antacid	antacid		antacid	n/a	n/a	331.11(g)(1)
hydriodic acid syrup						
cough/cold	cough/cold (expectorant)		expectorant	IISE	IISE	310.545(a)(6)(iii)
hydrochloric acid						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
hydrochloric acid diluted [see hydrochloric acid, diluted]						
=====	=====		=====	=====	=====	=====
hydrochloric acid, diluted						
miscellaneous internal	stomach acidifier		stomach acidifier	IIE	IIE	310.540(a)
hydrocodone bitartrate						
cough/cold	cough/cold (antitussive)		antitussive	IIS	IIS	[52 FR 30054]
hydrocortisone						
antimicrobial II	antifungal		anti-inflammatory	I combo	n/a	n/a
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIISE	defer	n/a
topical analgesic	external analgesic		antipruritic	I	I	pending

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hydrocortisone (0.25-5%)						
	miscellaneous external	external analgesic	dandruff/seborrheic dermatitis/psoriasis	n/a	I	pending
hydrocortisone (0.5-1%)						
	miscellaneous external	external analgesic	dandruff	n/a	IISE	pending
hydrocortisone acetate						
====		external analgesic	poison ivy/oak/sumac	n/a	I	pending
antimicrobial II		antifungal	anti-inflammatory (dissent)	I combo	n/a	n/a
miscellaneous external		antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external		antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external		dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IISE	defer	n/a
miscellaneous external		external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external		skin protectant	diaper rash	defer	n/a	pending
topical analgesic		external analgesic	antipruritic	I	I	pending
hydrocortisone acetate (0.25-5.0%)						
	miscellaneous external	external analgesic	dandruff/seborrheic dermatitis/psoriasis	n/a	I	pending
hydrocortisone acetate (0.25%-0.5%)						
	miscellaneous external	external analgesic	dandruff/seborrheic dermatitis /psoriasis	n/a	I	pending
hydrocortisone alcohol [see hydrocortisone]						
====	====	====	====	====	====	====

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hydrogen fluoride						
	dental	anticaries	anticavity dental rinse	n/a	IIISE	310.545(a)(2)(i)
hydrogen peroxide						
	antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending
	dental	oral mucosal injury	wound cleanser	I	I	pending
	dental	oral mucosal injury	wound healing agent	IIIIE	IIIIE	310.534(a)
	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IIISE	310.545(a)(10)(vii)
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IIISE	310.545(a)(18)(vi)(A)
	oral cavity	oral health care	antimicrobial	IIIIE	IIIIE	pending
	oral cavity	oral health care	debriding agent	III	III	pending
hydrogen peroxide and povidone iodine						
====		gingivitis/plaque	antiplaque/gingivitis	n/a	IIISE	pending
hydrogen peroxide and sodium bicarbonate						
====		gingivitis/plaque	antiplaque/gingivitis	n/a	IIISE	pending
hydrogen peroxide, sodium citrate, sodium lauryl sulfate, and zinc chloride						
====		gingivitis/plaque	antiplaque/gingivitis	n/a	IIISE	pending
hydroquinone						
	miscellaneous external	skin bleach	skin bleaching	I	I	pending

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hydroxyethyl cellulose						
ophthalmic	ophthalmic		demulcent	I	I	349.12(a)(2)
hydroxyethylcellulose [see hydroxyethyl cellulose]	=====	=====	=====	=====	=====	=====
hydroxypropyl methylcellulose [see hypromellose]	=====	=====	=====	=====	=====	=====
hyoscyamine sulfate						
laxative	antidiarrheal		antidiarrheal	IIISE	IIISE	310.545(a)(3)
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IIISE	310.545(a)(24)(i)
hypromellose						
ophthalmic	ophthalmic		demulcent	I	I	349.12(a)(3)
ibuprofen						
=====	internal analgesic		analgesic	n/a	I	[67 FR 54139]
=====	internal analgesic		antipyretic	n/a	I	[67 FR 54139]
ichthammol						
miscellaneous external	boil treatment		boil treatment	IIISE	IIISE	310.531(a)
miscellaneous external	corn/callus remover		corn/callus remover	IIISE	IIISE	[55 FR 33261]
impatiens biflora tincture						
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IIISE	310.545(a)(18)(vi)(A)

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	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
infusion of rose petal [see rose petal, infusion of]						
=====	=====	=====	=====	=====	=====	=====
inositol						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
iodine						
	miscellaneous external	wart remover	wart remover	IISE	IISE	[55 FR 33254]
	miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
oral cavity	oral health care	antimicrobial		IIISE	IIISE	pending
iodine complex/phosphate ester of alkylaryloxy polyethylene						
antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin wound cleanser	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	skin wound protectant	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	health care personnel handwash	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	preoperative skin preparation	IIISE	IIISE	pending	
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IIISE	pending	
antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending	

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iodine tincture						
	antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending
	antimicrobial I	antimicrobial	preoperative skin prep	I	I	pending
	antimicrobial I	antimicrobial	surgical hand scrub	IIS	IIS	pending
	antimicrobial I	antimicrobial	antimicrobial soap	n/a	IISE	pending
	antimicrobial I	antimicrobial	skin wound protectant	IISE	IIISE	pending
	antimicrobial I	antimicrobial	skin wound cleanser	IIS	IIIS	pending
	antimicrobial I	antimicrobial	skin antiseptic	IIS	IIIS	pending
	antimicrobial I	antimicrobial	health care personnel handwash	IISE	IISE	pending
iodine topical solution						
	antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending
iodized lime						
	cough/cold	cough/cold (expectorant)	expectorant	IISE	IISE	310.545(a)(6)(iii)
idoantipyrine						
	internal analgesic	internal analgesic	analgesic	IISE	IISE	310.545(a)(23)(i)
	internal analgesic	internal analgesic	antipyretic	IISE	IISE	310.545(a)(23)(i)
	internal analgesic	internal analgesic	antirheumatic	IISE	not OTC	310.545(a)(23)(i)
iodochlorhydroxyquin [see clioquinol]						
	=====	=====	=====	=====	=====	=====

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ippecac						
cough/cold	cough/cold (expectorant)	expectorant		IIE	IIE	310.545(a)(6)(iii)
ippecac fluidextract						
cough/cold	cough/cold (expectorant)	expectorant		IIE	IIE	310.545(a)(6)(iii)
miscellaneous internal	poison treatment	emetic		n/a	IIS	310.545(a)(16)
ippecac syrup						
cough/cold	cough/cold (expectorant)	expectorant		IIIIE	IIIIE	310.545(a)(6)(iii)
miscellaneous internal	emetic	emetic		I	I	pending
miscellaneous internal	poison treatment	emetic		n/a	I	pending
ippecac tincture						
miscellaneous internal	poison treatment	emetic		n/a	IIS	310.545(a)(16)
ipomea						
laxative	laxative	stimulant laxative		IIS	IIS	310.545(a)(12)(iv)(A)
iron ox bile						
miscellaneous internal	digestive aid	digestive aid (intestinal distress)		n/a	n/a	310.545(a)(18)(ii)
iron oxide						
miscellaneous external	antifungal	diaper rash		defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash		defer	n/a	pending
miscellaneous external	external analgesic	diaper rash		defer	n/a	310.545(a)(10)(iv)

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	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
isobornyl thiocyanoacetate						
	miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)
isobutaben						
	miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
isobutyl p-aminobenzoate [see isobutaben]						
=====	=====	=====	=====	=====	=====	=====
isoleucine						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
isopropyl alcohol						
	miscellaneous external	alcohols (topical)	antiseptic	I	I	pending
	miscellaneous external	mercury	first aid antiseptic	n/a	I	pending
	miscellaneous external	external analgesic	astringent	IISE	n/a	pending
	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
	miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)

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Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
isopropyl palmitate						
====		insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)
====		poison ivy/oak/sumac	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)
====		skin protectant	skin protectant	n/a	n/a	310.545(a)(18)(i)(B)
jalap						
laxative		laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)
johns wort						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
jojoba oil						
miscellaneous external	hair growth/loss		hair grower	n/a	IIE	310.527(a)
juniper						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
juniper oil (oil of juniper)						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
juniper tar						
====		antifungal	diaper rash	n/a	n/a	310.545(a)(22)(i)
====		antimicrobial	diaper rash	n/a	n/a	Pending
====		external analgesic	diaper rash	n/a	IISE	310.545(a)(10)(iv)
====		external analgesic	fever blister (topical)	n/a	I	Pending

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====	external analgesic		poison ivy/oak/sumac	n/a	I	pending
====	skin protectant		diaper rash	n/a	n/a	pending
hemorrhoidal	anorectal		counterirritant (external)	IIIE	n/a	n/a
hemorrhoidal	anorectal		analgesic (external)	n/a	I	346.16(b)
hemorrhoidal	anorectal		counterirritant (intrarectal)	IIIE	n/a	n/a
miscellaneous external	boil treatment		boil treatment	IISE	IIISE	310.531(a)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIIE	IIIIE	310.545(a)(7)
topical analgesic	external analgesic		analgesic/anesthetic	I	I	pending
juniper, extract						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
kaolin						
====	skin protectant		poison ivy/oak/sumac	n/a	I	347.10(j)
antacid	antacid		antacid	IIIIE	IIIIE	[39 FR 19873]
hemorrhoidal	anorectal		protectant (intrarectal)	I	I	346.14(5)
hemorrhoidal	anorectal		protectant (external)	I	I	346.14(5)
laxative	antidiarrheal		antidiarrheal	IIIIE	IIIIE	347.10(b)
miscellaneous external	skin protectant		diaper rash	n/a	I	pending
topical analgesic	skin protectant		skin protectant	I	I	347.10(j)

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Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
kaolin, colloidal						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
karaya [see karaya gum]	=====	=====	=====	=====	=====	=====
karaya gum						
laxative	laxative		bulk laxative	I	I	pending
miscellaneous internal	weight control		anorectic	IIIIE	IISE	310.545(a)(20)
kelp						
miscellaneous internal	weight control		anorectic	IIIIE	IISE	310.545(a)(20)
knotgrass						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
lactic acid						
contraceptive/vaginal	vaginal		lowers surface tension mucolytic effects	IIIIE	withdraw	n/a
contraceptive/vaginal	vaginal		alters vaginal pH	IIIIE	withdraw	n/a
miscellaneous external	wart remover		wart remover	IIIIE	IIIIE	[55 FR 33254]
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
lactobacillus acidophilus						
laxative	antidiarrheal		antidiarrheal	IIIIE	IIIIE	310.545(a)(3)(i)
miscellaneous internal	fever blister (oral)		fever blister/oral	IIIIE	IIIIE	310.537(a)

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lactobacillus bulgaricus						
laxative		antidiarrheal	antidiarrheal	IIIIE	IIIIE	310.545(a)(3)(i)
miscellaneous internal	fever blister (oral)		fever blister/oral	IIIIE	IIIIE	310.537(a)
lactose						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
lanolin						
====		skin protectant	skin protectant	n/a	n/a	347.10(k)
hemorrhoidal		anorectal	protectant (external)	I	I	346.14(6)
hemorrhoidal		anorectal	protectant (intrarectal)	I	I	346.14(6)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	boil treatment		boil treatment	IISE	IISE	310.531(a)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	hair growth/loss		hair grower	IIE	IIE	310.527(a)
miscellaneous external	skin protectant		diaper rash	defer	I	pending
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	n/a

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	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)
lanolin (in combination)						
ophthalmic	ophthalmic	emollient	I	I	349.14(a)(2)	
lanolin alcohol [see lanolin alcohols]						
====	====	====	====	====	====	====
lanolin alcohols						
hemorrhoidal	anorectal	protectant (external)	I	IISE	310.545(a)(26)(viii)	
hemorrhoidal	anorectal	protectant (intrarectal)	I	IISE	310.545(a)(26)(viii)	
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending	
miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending	
lanolin anhydrous [see lanolin, anhydrous]						
====	====	====	====	====	====	====
lanolin nonionic derivatives						
ophthalmic	ophthalmic	emollient	I	I	349.14	
lanolin, anhydrous (in combination)						
ophthalmic	ophthalmic	emollient	I	I	349.14(a)(1)	
lappa extract						
hemorrhoidal	anorectal	anorectal (external)	IISE	IISE	310.545(a)(26)(vii)	
hemorrhoidal	anorectal	anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(vii)	

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laureth 10s						
contraceptive/vaginal	contraceptive (vaginal)		contraceptive	III	E	withdraw 310.545(a)(28)
lauric diethanolamide						
miscellaneous external	hair growth/loss		hair grower	II	S	n/a 310.527(a)
lauryl isoquinolinium bromide						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff		III	E	310.545(a)(7)
lavender compound, tincture of						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
lavender oil						
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
lawsone with dihydroxyacetone						
topical analgesic	sunscreen		sunscreen	I	I	310.545(a)(29)
L-desoxyephedrine [see desoxyephedrine, L-]						
=====	=====		=====	=====	=====	=====
lead acetate						
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	I	310.545(a)(10)(vii)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	I	310.545(a)(18)(vi)(A)

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lecithin						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
lemon oil (terpeneless)						
	miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)
leptandra extract						
hemorrhoidal		anorectal	anorectal (external)	IISE	IISE	310.545(a)(26)(vii)
hemorrhoidal		anorectal	anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(vii)
leucine						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
levmetamfetamine						
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant))	IIIIE	I	341.20(b)(1)
levomethamphetamine [see desoxyephedrine, l-]						
=====	=====	=====	=====	=====	=====	=====
licorice						
	miscellaneous internal	aphrodisiac	aphrodisiac	IISE	IISE	310.528(a)
licorice root extract						
	miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)
lidocaine						
hemorrhoidal		anorectal	anesthetic (external)	IIIIE	I	346.10(f)

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	hemorrhoidal	anorectal	anesthetic (intrarectal)	IIIIE	IIIIE	[55 FR 1779]
	miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
	miscellaneous external	male genital desensitizer	male genital desensitizer	I	I	348.10(a)(2)
	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	I	pending
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
	oral cavity	oral health care	analgesic/anesthetic	IIS	IIS	310.545(a)(14)
	topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
lidocaine hydrochloride						
	====	external analgesic	poison ivy/oak/sumac	n/a	I	pending
	miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
	oral cavity	oral health care	analgesic/anesthetic	IIS	IIS	310.545(a)(14)
	topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
linden						
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
lipase						
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
live yeast cell derivative						
	====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)
	====	poison ivy/oak/sumac	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)

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	topical analgesic	skin protectant	skin protectant	IIIIE	IIIIE	310.545(a)(18)(i)(B)
liver concentrate						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
lobeline						
	miscellaneous internal	smoking deterrent	smoking deterrent	IIIIE	IIIIE	310.544(d)
lysine						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
lysine aspirin						
	internal analgesic	internal analgesic	analgesic	n/a	IISE	310.545(a)(23)(i)
lysine hydrochloride						
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
	miscellaneous internal	fever blister (oral)	fever blister/oral	IIIIE	IIIIE	310.537(a)
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
magaldrate						
	antacid	antacid	antacid	I	I	331.11(g)(2)
magnesium						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
magnesium aluminum silicate						
	antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)

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antacid	antacid		antacid	I	I	331.11(g)(3) 331.11(k)(2)(1)
magnesium aluminumsilicate [see magnesium aluminum silicate]						
=====	=====	=====	=====	=====	=====	=====
magnesium carbonate						
antacid	antacid		antacid	I	I	331.11(g)(4)
internal analgesic	internal analgesic		corrective	I	n/a	n/a
miscellaneous external antifungal			diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external antimicrobial			diaper rash	defer	n/a	pending
miscellaneous external external analgesic			diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external skin protectant			diaper rash	defer	n/a	pending
miscellaneous internal overindulgence in alcohol/food			overindulgence remedies (hangover)	I	I	pending
magnesium citrate						
laxative	laxative		saline laxative (oral solution)	I	I	pending
magnesium glycinate						
antacid	antacid		antacid	I	I	331.11(g)(5)
magnesium hydroxide						
antacid	antacid		antacid	I	I	331.11(g)(6)
internal analgesic	internal analgesic		corrective	I	n/a	pending
laxative	laxative		saline laxative	I	I	pending

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	miscellaneous internal	digestive aid	digestive aid (ippuad)	IIIIE	IIIIE	310.545(a)(8)(i)
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIIIE	IIIIE	310.545(a)(8)(i)
magnesium oxide						
	antacid	antacid	antacid	I	I	331.11(g)(7)
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
magnesium salicylate						
	internal analgesic	internal analgesic	analgesic	I	I	pending
	internal analgesic	internal analgesic	antipyretic	I	I	pending
	internal analgesic	internal analgesic	antirheumatic	I	not OTC	n/a
	miscellaneous internal	menstrual/diuretic	analgesic	I	I	pending
magnesium sulfate						
	antimicrobial II	acne	acne	IIE	IIE	310.545(a)(1)
	laxative	laxative	saline laxative	I	I	pending
	miscellaneous external	boil treatment	boil treatment	IISE	IIISE	310.531(a)
	miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
magnesium trisilicate						
	antacid	antacid	antacid	I	I	331.11(g)(8) 331.11(k)(3)(1)
	miscellaneous internal	digestive aid	digestive aid (ippuad)	IIIIE	IIIIE	310.545(a)(8)(i)
	miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending

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malt						
	miscellaneous internal	weight control	anorectic	I	I	310.545(a)(20)
malt soup extract						
laxative	laxative		bulk laxative	I	I	pending
maltodextrin						
	miscellaneous internal	weight control	anorectic	I	I	310.545(a)(20)
mandrake						
	miscellaneous internal	aphrodisiac	aphrodisiac	n/a	n/a	310.528(a)
manganese citrate						
	miscellaneous internal	weight control	anorectic	I	I	310.545(a)(20)
mannitol						
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
	miscellaneous internal	weight control	anorectic	I	I	310.545(a)(20)
meclizine hydrochloride						
laxative	antiemetic		antiemetic	I	I	336.10(d)
menfegol						
contraceptive/vaginal	contraceptive (vaginal)		contraceptive (dissent)	I	withdraw	n/a
menthol						
antimicrobial II	antifungal		antifungal	I	I	310.545(a)(22)(ii)

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cough/cold	cough/cold (antitussive)	antitussive (mouthwash)	IIIIE	IIIIE	[52 FR 30055]
cough/cold	cough/cold (antitussive)	antitussive (topical/inhalant)	IIIIE	I	341.14(b)(2)
cough/cold	cough/cold (antitussive)	antitussive (lozenge)	IIIIE	I	341.14(b)(2)
cough/cold	cough/cold (expectorant)	expectorant (topical/inhalant)	IIIIE	IIIIE	310.545(a)(6)(iii)
cough/cold	cough/cold (expectorant)	expectorant (lozenge)	IIIIE	IIIIE	310.545(a)(6)(iii)
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (lozenge)	IIIIE	IIIIE	[59 FR 43408]
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (mouthwash)	IIIIE	IIIIE	310.545(a)(6)(ii)(A)
dental	relief of oral discomfort	toothache relief	IIS	IIS	pending
hemorrhoidal	anorectal	analgesic (external)	n/a	I	346.16(c)
miscellaneous external	antifungal	diaper rash	defer	IISE	310.545(a)(22)(ii)
miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIIE	IIIIE	310.545(a)(7)
miscellaneous external	analgesic	astringent	IISE	n/a	pending
miscellaneous external	analgesic	diaper rash	defer	IISE	310.545(a)(10)(iv)
miscellaneous external	analgesic	insect bite/sting	IISE	I	pending
miscellaneous external	analgesic	poison ivy/oak/sumac	defer	I	pending
miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
miscellaneous external	skin protectant	fever blister (topical)	defer	defer	pending

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	miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
	miscellaneous external	wart remover	wart remover	IISE	IISE	[55 FR 33254]
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)
oral cavity	oral health care	antimicrobial	IIIIE	IIIIE	pending	
oral cavity	oral health care	analgesic/anesthetic	I	I	pending	
topical analgesic	external analgesic	counterirritant	I	I	pending	
topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending	
menthol (0.1 to 1.0%)						
	miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
menthol (1.25 to 16%)						
	miscellaneous external	external analgesic	fever blister (topical)	defer	IIIIE	310.545(a)(10)(v)
hemorrhoidal	anorectal	counterirritant (intrarectal)	IIE	IIE	310.545(a)(26)(iv)	
hemorrhoidal	anorectal	counterirritant (external)	I	IIIE	310.545(a)(26)(iv)	
menthyl anthranilate [see meradimate]						
=====	=====	=====	=====	=====	=====	=====
meradimate						
topical analgesic	sunscreen	sunscreen	I	I	352.10(h)	

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meralein sodium						
oral cavity	oral health care		antimicrobial	IISE	IISE	pending
merbromin						
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)
miscellaneous external	mercury		antiseptic	IISE	IISE	310.545(a)(27)(i)
merbromin (mercurochrome)						
miscellaneous external	mercury		first aid antiseptic	n/a	IIIIE	310.545(a)(27)(i)
mercufenol chloride						
miscellaneous external	mercury		first aid antiseptic	n/a	IIIIE	310.545(a)(27)(i)
miscellaneous external	mercury		antiseptic	IISE	IISE	310.545(a)(27)(i)
miscellaneous external	antimicrobial		first aid antiseptic	n/a	IIS	310.545(a)(27)(i)
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
mercuric chloride [see calomel]						
=====	=====		=====	=====	=====	=====
mercuric oxide, yellow						
miscellaneous external	mercury		first aid antiseptic	n/a	IISE	310.545(a)(27)(i)
miscellaneous external	mercury		antiseptic	IISE	IISE	310.545(a)(27)(i)

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	ophthalmic	ophthalmic	anti-infective	IIISE	IIISE	310.545(a)(21)(ii)
mercuric salicylate						
	miscellaneous external mercury		first aid antiseptic	n/a	IIISE	310.545(a)(27)(i)
	miscellaneous external mercury		antiseptic	IIISE	IIISE	310.545(a)(27)(i)
mercuric sulfide, red						
	miscellaneous external mercury		first aid antiseptic	n/a	IIISE	310.545(a)(27)(i)
	miscellaneous external mercury		antiseptic	IIISE	IIISE	310.545(a)(27)(i)
mercurous chloride [see calomel]						
=====	=====		=====	=====	=====	=====
mercury						
	miscellaneous external mercury		first aid antiseptic	n/a	IIISE	310.545(a)(27)(i)
	miscellaneous external mercury		antiseptic	IIISE	IIISE	310.545(a)(27)(i)
mercury (any ingredient)						
=====	antimicrobial		diaper rash	defer	n/a	310.545(a)(27)(ii)
=====	contraceptive (vaginal)		contraceptive	n/a	n/a	310.545(a)(28)
mercury chloride [see mercuric chloride]						
=====	=====		=====	=====	=====	=====
mercury oleate						
	miscellaneous external mercury		first aid antiseptic	n/a	IIISE	310.545(a)(27)(i)

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	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	psoriasis	IIE	IIE	310.545(a)(7)
	miscellaneous external	mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)
mercury, ammoniated						
	miscellaneous external	antimicrobial	first aid antiseptic	n/a	IISE	310.545(a)(27)(i)
	miscellaneous external	skin bleach	skin bleaching	IISE	IISE	310.545(a)(17)
	miscellaneous external	mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)
metaproterenol sulfate						
cough/cold		cough/cold (bronchodilator)	bronchodilator	n/a	III	310.545(a)(6)(iv)(A)
methapyrilene						
	miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
methapyrilene fumarate						
cough/cold		cough/cold (antihistamine)	antihistamine	I	IIS	310.545(a)(6)(i)(A)&(B)
internal analgesic		internal analgesic	analgesic adjuvant	IIIIE	IIS	310.545(a)(23)(i)
internal analgesic		internal analgesic	antihistamine	IIE	n/a	310.545(a)(6)(A)
internal analgesic		internal analgesic	antipyretic adjuvant	IIIIE	IIS	310.545(a)(23)(i)
internal analgesic		internal analgesic	antirheumatic adjuvant	IIIIE	IIS	310.545(a)(23)(i)

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Ingredient			Drug Category	ANPR	PR	FR
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sedative	daytime sedative		sedative	IIISE	IISE	310.519(a)
sedative	nighttime sleep aid		sleep aid	IIISE	IIS	[54 FR 6826]
methapyrilene hydrochloride						
====	external analgesic		poison ivy/oak/sumac	n/a	IISE	310.545(a)(10)(vii)
cough/cold	cough/cold (antihistamine)		antihistamine	I	IIS	310.545(a)(6)(i)(A)&(B)
miscellaneous external	external analgesic		fever blister (topical)	defer	IIE	310.545(a)(10)(v)
miscellaneous internal	menstrual/diuretic		menstrual	n/a	IISE	310.545(a)(24)(i)
sedative	nighttime sleep aid		sleep aid	IIISE	IIS	[54 FR 6826]
sedative	daytime sedative		sedative	IIISE	IIS	310.519(a)
topical analgesic	external analgesic		analgesic/anesthetic	I	IIS	310.545(a)(10)(i)
methenamine						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
methionine						
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
miscellaneous internal	weight control		anorectic	IIISE	IISE	310.545(a)(20)

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methoxyphenamine hydrochloride						
cough/cold		cough/cold (bronchodilator)	bronchodilator	I	IIIE	310.545(a)(6)(iv)(A)
methoxypolyoxyethylene glycol 550 laurate						
contraceptive/vaginal		contraceptive (vaginal)	contraceptive	IIIIE	IIIIE	310.545(a)(28)
methyl nicotinate						
miscellaneous external	external analgesic		fever blister (topical)	defer	IIIE	310.545(a)(10)(v)
topical analgesic	external analgesic		counterirritant	I	I	pending
methyl salicylate						
dental	relief of oral discomfort		toothache relief	IIISE	IIISE	pending
dental	relief of oral discomfort		oral mucosal analgesic	IIISE	IIISE	pending
miscellaneous external	boil treatment		boil treatment	IIISE	IIISE	310.531(a)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff		IIIIE	IIIIE	310.545(a)(7)
miscellaneous external	external analgesic		astringent	n/a	n/a	pending
miscellaneous external	external analgesic		fever blister (topical)	defer	IIIE	310.545(a)(10)(v)
miscellaneous external	skin protectant		astringent	IIISE	IIISE	310.545(a)(18)(ii)
miscellaneous external	corn/callus remover		corn/callus remover	IIISE	IIISE	[55 FR 33261]
miscellaneous internal	smoking deterrent		smoking deterrent	IIE	IIE	310.544(d)
oral cavity	oral health care		antimicrobial	IIIIE	IIIIE	pending
oral cavity	oral health care		analgesic/anesthetic	IIIIE	IIIIE	310.545(a)(14)

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	topical analgesic	external analgesic	counterirritant	I	I	pending
methylbenzethonium chloride						
antimicrobial I	antimicrobial		first aid antiseptic	n/a	I	pending
antimicrobial I	antimicrobial		antimicrobial soap	n/a	IISE	pending
antimicrobial I	antimicrobial		skin antiseptic	IIISE	IIISE	pending
antimicrobial I	antimicrobial		skin protectant	IIISE	IIISE	pending
antimicrobial I	antimicrobial		preoperative skin prep	IIISE	IIISE	pending
antimicrobial I	antimicrobial		skin wound cleanser	I	I	pending
antimicrobial I	antimicrobial		surgical hand scrub	IIISE	IIISE	pending
antimicrobial I	antimicrobial		health care personnel handwash	IIIIE	IIIIE	pending
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	IIISE	pending
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis		cradle cap	IIIIE	IIIIE	310.545(a)(7)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
miscellaneous external	corn/callus remover		corn/callus remover	IIISE	IIISE	[55 FR 33261]
methylcellulose						
antacid	antacid		antacid	IIIIE	IIIIE	[39 FR 19873]
laxative	laxative		bulk laxative	I	I	pending

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	miscellaneous internal	weight control	anorectic	IIIIE	IISE	310.545(a)(20)
ophthalmic	ophthalmic		demulcent	I	I	349.12(a)(4)
methylene blue						
	miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
methylparaben						
antimicrobial II		antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)
methyltestosterone						
	miscellaneous internal	aphrodisiac	aphrodisiac	IIS	IIS	310.528(a)
miconazole nitrate						
antimicrobial II		antifungal	anticandidal	I	n/a	n/a
antimicrobial II		antifungal	antifungal	I	I	333.210(c)
microporous cellulose [see cellulose, microporous]						
=====	=====	=====	=====	=====	=====	=====
milk solids, dried						
antacid		antacid	antacid	I	I	331.11(h)
mineral oil						
hemorrhoidal		anorectal	protectant (external)	I	I	346.14(7)
hemorrhoidal		anorectal	protectant (intrarectal)	I	I	346.14(7)
laxative		laxative	lubricant laxative	I	I	pending

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		miscellaneous external antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
		miscellaneous external antimicrobial	diaper rash	defer	n/a	pending
		miscellaneous external external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
		miscellaneous external external analgesic	fever blister (topical)	defer	n/a	n/a
		miscellaneous external skin protectant	diaper rash	defer	I	pending
		miscellaneous external skin protectant	fever blister (topical)	defer	n/a	pending
ophthalmic	ophthalmic		emollient	I	I	349.14(b)(2)
mineral oil, emulsified [see mineral oil]						
=====	=====	=====	=====	=====	=====	=====
mineral oil, light						
ophthalmic	ophthalmic		emollient	I	I	349.14(b)(1)
minerals						
miscellaneous internal	aphrodisiac		aphrodisiac	n/a	IISE	310.528(a)
mono-and di-glycerides						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
mullein						
hemorrhoidal	anorectal		anorectal (external)	IISE	IISE	310.545(a)(26)(vii)
hemorrhoidal	anorectal		anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(vii)

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mustard oil [see allyl isothiocyanate]	=====	=====	=====	=====	=====	=====
mycozyme						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
myrrh						
dental	relief of oral discomfort		oral mucosal protectant	IIISE	IIISE	pending
myrrh tincture						
oral cavity	oral health care		antimicrobial	IISE	IISE	310.545(a)(14)
oral cavity	oral health care		astringent	IISE	IISE	pending
myrrh tincture of [see myrrh tincture]	=====	=====	=====	=====	=====	=====
myrrh, fluid extract of						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
naphazoline hydrochloride						
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (topical/inhalant))	I	I	341.20(b)(6)
ophthalmic	ophthalmic		vasoconstrictor	I	I	349.18(b)
natural estrogenic hormone						
miscellaneous internal	menstrual/diuretic		menstrual	n/a	IISE	310.545(a)(24)(i)

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neomycin sulfate						
antimicrobial II	antibiotic		skin wound protectant	IIIIS	defer	n/a
neomycin sulfate (cream)						
antimicrobial II	antibiotic		first aid antibiotic	n/a	I	333.110(e)
neomycin sulfate (ointment)						
antimicrobial II	antibiotic		first aid antibiotic	n/a	I	333.110(d)
nettle						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
niacinamide						
miscellaneous internal	menstrual/diuretic		menstrual	n/a	IISE	310.545(a)(24)(i)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
sedative	daytime sedative		sedative	IIE	IISE	310.519(a)
nickel-pectin						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
nitromersol						
miscellaneous external	mercury		first aid antiseptic	n/a	IISE	310.545(a)(27)(i)
miscellaneous external	mercury		antiseptic	IISE	IISE	310.545(a)(27)(i)
oral cavity	oral health care		antimicrobial	IISE	IISE	pending

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nonoxynol 9						
	contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	I	withdraw	n/a
	contraceptive/vaginal	vaginal	minor irritations	IIIIE	withdraw	n/a
	contraceptive/vaginal	contraceptive (vaginal)	contraceptive	I	withdraw	n/a
nonylphenoxy poly (ethyleneoxy) ethanol iodine						
antimicrobial I	antimicrobial		surgical hand scrub	IIISE	IIISE	pending
antimicrobial I	antimicrobial		antimicrobial soap	n/a	IIISE	pending
antimicrobial I	antimicrobial		health care personnel handwash	IIISE	IIISE	pending
antimicrobial I	antimicrobial		skin wound cleanser	IIISE	IIISE	pending
antimicrobial I	antimicrobial		preoperative skin prep	IIISE	IIISE	pending
antimicrobial I	antimicrobial		skin antiseptic	IIISE	IIISE	pending
noscapine						
cough/cold	cough/cold (antitussive)	antitussive		IIIIE	IIIIE	[52 FR 30054]
noscapine hydrochloride						
cough/cold	cough/cold (antitussive)	antitussive		IIIIE	IIIIE	[52 FR 30054]
nucleic acids						
miscellaneous external	hair growth/loss	hair grower		n/a	n/a	310.527(a)
nutmeg oil (oil of nutmeg)						
miscellaneous internal	menstrual/diuretic	diuretic		n/a	IIISE	310.545(a)(24)(i)

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nux vomica						
miscellaneous internal	aphrodisiac		aphrodisiac	I	I	310.528(a)
nux vomica extract						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
nystatin						
antimicrobial II	antifungal		anticandidia	I	II	310.545(a)(22)(iv)
obtundia surgical dressing						
miscellaneous external	external analgesic		insect bite/sting	I	I	pending
miscellaneous external	skin protectant		insect bite/sting	I	I	pending
octinoxate						
topical analgesic	sunscreen		sunscreen	I	I	352.10(j)
octisalate						
topical analgesic	sunscreen		sunscreen	I	I	352.10(k)
octocrylene						
topical analgesic	sunscreen		sunscreen	I	I	352.10(i)
octoxynol 9						
contraceptive/vaginal	vaginal		minor irritations	III	withdraw	310.545(a)(28)(ii)
contraceptive/vaginal	vaginal		lowers surface tension mucolytic effects	I	withdraw	310.545(a)(28)(ii)
contraceptive/vaginal	contraceptive (vaginal)		contraceptive	I	withdraw	310.545(a)(28)(ii)

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octyl salicylate [see octisalate]	=====	=====	=====	=====	=====	=====
octyldodecanol						
miscellaneous external external analgesic			fever blister (topical)	defer	n/a	n/a
miscellaneous external skin protectant			fever blister (topical)	defer	n/a	pending
octylmethoxycinnamate [see octinoxate]	=====	=====	=====	=====	=====	=====
oil of erigeron						
miscellaneous internal menstrual/diuretic			diuretic	n/a	I ISE	310.545(a)(24)(i)
olive oil						
miscellaneous external hair growth/loss			hair grower	I ISE	n/a	310.527(a)
opium powder [see opium, powdered]	=====	=====	=====	=====	=====	=====
opium tincture						
laxative	antidiarrheal		antidiarrheal	I	I ISE	310.545(a)(3)(i)
opium, tincture of [see opium tincture]	=====	=====	=====	=====	=====	=====
opium, powdered						
laxative	antidiarrheal		antidiarrheal	I	I ISE	310.545(a)(3)(i)

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organic vegetables						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
orthophosphoric acid						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
orthophosphoric acid [see phosphoric acid]						
=====	=====		=====	=====	=====	=====
ox bile						
laxative	laxative		stimulant laxative	IIISE	IIISE	310.545(a)(12)(iv)(A)
ox bile extract						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IIE	IIE	310.545(a)(8)(i))
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIE	IIE	310.545(a)(8)(i)
oxybenzone						
topical analgesic	sunscreen		sunscreen	I	I	352.10(l)
oxymetazoline hydrochloride						
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (topical/inhalant)	I	I	341.20(b)(7)
oxyquinoline						
antimicrobial II	antifungal		antifungal	IIISE	IIISE	310.545(a)(22)(ii)
miscellaneous external	antifungal		diaper rash	defer	IISE	310.545(a)(22)(ii)
miscellaneous external	antimicrobial		diaper rash	defer	IIISE	pending

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	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
	oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending
oxyquinoline citrate						
	contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a
oxyquinoline sulfate						
	antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)
	contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a
	miscellaneous external	boil treatment	boil treatment	IIISE	IIISE	310.531(a)
	miscellaneous external	external analgesic	astringent	IIISE	n/a	n/a
	miscellaneous external	skin protectant	astringent	IIISE	IIISE	310.545(a)(18)(ii)
oxyquinoline sulfate [see oxyquinoline]						
=====	=====	=====	=====	=====	=====	=====
oxytetracycline hydrochloride						
	antimicrobial II	antibiotic	first aid antibiotic	n/a	I	333.120 [combos]
	antimicrobial II	antibiotic	skin wound antibiotic	IIIIE	defer	n/a
	antimicrobial II	antibiotic	skin wound protectant	I	defer	n/a

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ozokerite						
	miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	n/a
	miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	n/a